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2014 Agricultural Biotechnology Report for Panama

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Report Highlights:
Panama has approved the imports of GM corn seeds for local production, and has conducted GM mosquitoes and salmon field tests. Other two products are pending for approval: import of GM rice for human consumption and GM flies for screwworm research. The new Government Administration will have the challenge to approve those products, also the GM salmon for commercialization and the establishment of implementing regulations for the laws on biosafety and biotechnology.

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Section I. Executive Summary:

Panama is a net food importer and the United States is by far its main supplier. During calendar year 2013, exports of U.S. agricultural, fish & forestry products to Panama exceeded $673 million, increasing 14.8% the exports of the previous year ($511.8 million on 2012). The U.S-Panama Trade Promotion Agreement entered into force on October 31, 2012. USDA estimates that the agreement, fully implemented, will boost U.S. agricultural sales by an additional $50 million annually.

The most important U.S. products exported to Panama for year 2013 were [i]:
Consumer Oriented foods……...…..$360.0 million
Intermediate products (soybean meal, oil, flour, and seeds).....$146.9 million
Grains in Bulk……..……..$133.2 million
Forest products…..……...…...…$12.8 million
Fish products…….……...…..$3.3 million

[i] Data Source: U.S. Census Bureau Trade Data, Foreign Trade Statistics

The future looks bright for exports of U.S. food products to Panama due to the forecasted extraordinary growth of the Panamanian economy of 7.5% in 2014. Due to the Trade Promotion Agreement between the two countries, U.S. food products will have increased access to the Panamanian market at zero percent duties once tariff phase-outs run their course completely.

By category, consumers prefer the "ready to eat products", such as snack foods, processed fruits and vegetables, and turkey ham, as the most popular. Bulk agricultural products are also important, among them: yellow corn and soybean meal for animal feed and wheat and rice for human consumption. Panama imports a large amount of rice (approximately 182,388 metric tons annually). In the past years the United States held 99 percent of the imported rice market.

Panama is a party to the Cartagena Protocol on Biosafety, as adopted by the Law 72 of 2001. And Panama ratified the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress.

However, the Government of Panama (GOP) delayed establishing the implementing regulations of the law, which created the National Commission of Biosafety for Genetically Modified Organisms. Currently, the absence of clear procedures regarding the approval process and coordination among all

the competent government agencies in charge of authorizing the import of Genetically Modified Organisms (GMO's) into Panama has been causing delays on the approval of four GMO events, requested to the Government through the National Commission of Biosafety for Genetically Modified Organisms.

The new Government Administration, led by President Juan Carlos Varela, started on July 1st, 2014 up to June 30, 2019, will have the challenge to establish the implementing regulations for the laws on biosafety and biotechnology.

Last year, there were some consumer concerns about the presence of biotech products in the food supply. There were several news articles in newspapers, TV news, magazines, as well as some consumers and private sector representatives criticizing their use in Panama.

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: Production and Trade

a) PRODUCTS DEVELOPMENT:

The GOP, through Resolution CNB No. 05-2012 of August 2, 2012 of the National Commission of Biosafety for Genetically Modified Organisms of Panama, published on the Official Gazette No. 27105-A, has authorized the cultivation with DuPont-Pioneer's "Herculex I" (DAS-01507-1) Corn seeds, to the local corn producers but using the Biosafety and Management Plan for controlled planting. This plan was published at the Official Gazette No. 27340-B through the Ministry of Agricultural Development Resolution DAL -024-ADM-2013 of June 20, 2013. Previously, the GOP conducted two official field-testing, on the agricultural crop year 2012-2013 in the province of Los Santos, Panama, using 2,011 bags of the Herculex I corn seed with the technical supervision of the Panamanian Agricultural Research Institute (IDIAP, in Spanish) and the assistance of the Panamanian importing company, Melo and Co.

On the first field-test the GOP evaluated: an assessment of pollen dispersal; assessment of populations of insects on crops of corn Herculex I; evaluation of biological efficacy; and agronomic validation. And on the second field-testing the GOP made another evaluation of biological efficacy.

However, after all this procedure and coordination with Melo and Co., the U.S. exporter DuPont – Pioneer decided not to export directly the 2,500 bags with 60,000 Herculex I corn seeds per bag, which was to be planted for the planting period of August – September 2013. It had been agreed to start the first crop with 20 selected producers of the Province of Los Santos in Panama, with a 10 % higher sales price than the traditional corn seed ($182.00 per bag approximately), in a production area of 2,350 hectares, forecasting a production yield of 15,876 Metric Tons. The decision was made by DuPont – Pioneer, because the Herculex I corn seed was approved only for controlled planting for animal feed consumption, not for food consumption. Additionally, this planting did not take place because of the absence of clear procedures regarding the approval process and coordination among the Ministry of Agricultural Development's Plant Health National Direction and the National Committee of Seeds for authorizing the Registration of a genetically modified seed, which is a legal requirement for the

commercialization of any seed in Panama, not only for a GMO.

The Panamanian importing company, Melo and Co. will continue their efforts with the Biosafety Committee on Public Health for the approval of Herculex I for food consumption; and with the National Committee of Seeds for its registration for commercialization, which they would like to start on this year 2014 in Panama. The entrance of the new GOP administration, and therefore new Commissioners, has delayed this process.

In May 2010, the National Commission of Biosafety for Genetically Modified Organisms of Panama received the formal request for the approval of the genetically modified rice for human consumption from Bayer's Crop Science LLRice62. Bayer's request for the rice to be analyzed and approved has been facing delays, especially at the Biosafety Committee on Public Health for Panama, whose chairman is the Director General for Public Health of the Ministry of Health in Panama and the majority of its members also belongs to the Ministry of Health.

It is important to note that all the documentation to be sent to the Biosafety Committee on Public Health for Panama must be sent in Spanish, as its members does not speak English.

b) COMMERCIAL PRODUCTION:

The only GM product approved for commercially cultivation is the DuPont-Pioneer's "Herculex I" (DAS-01507-1) Corn seeds. However, it has not been commercialized yet, due to the reason explained on the above paragraphs.

c) EXPORTS:

Panama does not export any GE crops/products to any country.

d) IMPORTS:

Panama is waiting to receive from DuPont-Pioneer the "Herculex I" (DAS-01507-1) Corn seeds, once all the local legal requirements are fulfilled, as explained on the above paragraphs.

e) FOOD AID RECIPIENT COUNTRY:

Panama is not a currently food aid recipient.

PART B: Policy

a) REGULATORY FRAMEWORK:

The National Authority for the Environment (ANAM) is the Focal Point of the Cartagena Protocol on Biosafety in Panama.

The National Commission of Biosafety for Genetically Modified Organisms of Panama, is composed by:

1) Competent National Authorities:
-Ministry of Agricultural Development (MIDA, in Spanish)
-Ministry of Health (MINSA, in Spanish)
-Ministry of Commerce and Industry (MICI, in Spanish)
-Ministry of Foreign Relations (MIRE, in Spanish)
-National Authority for the Environment (ANAM, in Spanish)
-Panamanian Food Safety Authority (AUPSA, in Spanish)
-Authority of the Aquatic Resources of Panama (ARAP, in Spanish)

2) Institutions for Technical Support:
-National Secretariat for Science, Technology and Innovation. (SENACYT, in Spanish)
-Institute of Scientific Research and High Technology Services (INDICASAT AIP.)
-Agricultural Research Institute of Panama (IDIAP, in Spanish)
-Technological University of Panama (UTP, in Spanish)
-University of Panama
-Gorgas Memorial Institute for Health Studies.
-Authority of Free Competition and Consumer Rights (ACODECO, in Spanish)

The current objectives of the Commission are:
1. Promote and monitor the implementation of the law that will amend the Law 48 of 2002, which creates the National Commission for Biosafety of genetically modified organisms.
2. Develop, promote and monitor the compliance of the regulations and manuals of procedures for the genetically modified organisms.
3. Strengthen and monitor the Biosafety Clearing House (BCH) of Panama
4. Propose the establishment of capacity building in the institutions for Biosafety of Genetically Modified Organisms.

The National legal framework for GMO's is based on the following laws:
1) Law 72 of December 26, 2001, by which Panama approved the Cartagena Protocol on Biosafety entered into force on January 29, 2000.
2) Law 48 of August 8, 2002that creates the National Commission of Biosafety for Genetically Modified Organisms, and dictates other dispositions.
3) Law 47 of 1996, establishing that for the import, export, research, experiment, release to the environment, reproduction and commercialization of transgenic plants, bio-control agents and seeds for production, and the National Direction of Plant Health has approval.
4) Law 23 of 1997, which regulates the Animal Health and Agricultural Quarantine.
5) Law Decree 11 of February 22, 2006, which creates the Panamanian Food Safety Authority (AUPSA) and the dispositions for the import, transit and trans-boundary movement of food and feed into Panama.

The Law 72 of 2001, being an international agreement, is in force but has not been fully implemented.

The Law 48 of 2002 was implemented on February 26, 2011 with a first meeting of Commissioners. The Commission Presidency is to be rotated among the Ministers, this year the Presidency of the Commission is going to be on the Minister of Environment (ANAM), Mrs. Mirei Endara. The Commission is in charge to draft and implement the regulations for use, import, commercialization, and research of genetically modified organisms, and oversight of all aspects of production, introduction, consumption, etc. of all biotech products, and is to make a priority of the Cartagena Protocol and the precautionary principle.

The National Commission of Biosafety for Genetically Modified Organisms of Panama will not directly authorize the use, production, introduction or consumption of a genetically modified organisms (GMO) in Panama, but it will recommend the competent authority to approve or not the use, production, introduction, research or consumption of a GMO in Panama, and will recommend the adoption of Biosafety and Management Plan for genetically modified organisms.

Under the National Commission of Biosafety for Genetically Modified Organisms of Panama, are three Biosafety Committees, which have to conduct risk analysis and risk assessments, case by case and step by step, with science-based evidence. Depending on the type and use of the GMO, the respective Committee will be in charge to pursue the analysis and assessments:

a) **Biosafety Committee on Agriculture**: For conducting risk analysis, risk assessments, monitoring and tracking of all activities for use, research, restricted management, laboratory testing, release to the environment, greenhouse, net house and experimental batches of GMO for agricultural use (i.e. seeds, feeds consumption).

b) **Biosafety Committee on Public Health:** For conducting risk analysis, risk assessments, monitoring and tracking of all activities for use, research, restricted management, laboratory testing, release to the environment, technological development of genetically modified organisms that may affect human health. (i.e. food consumption, or GM animals to be used on Public Health research).

c) **Biosafety Committee on Environment**: For conducting risk analysis, risk assessments, monitoring and tracking of all activities for use, research, restricted management, laboratory testing, release to the environment, greenhouse, net house and experimental batches of GMO for research; and use of raw material for feed consumption, ornament and bioremediation through microorganisms.

The competent authorities who will have to make the final decision, depending on the recommendation of the National Commission of Biosafety for Genetically Modified Organisms of Panama, are the following ministries and authorities, with their respective scope of jurisdiction:

• The **Ministry of Agricultural Development (MIDA)** is the competent national authority to regulate, control, approve and monitor the use, import, export, research, experiment, release to the environment, reproduction and commercialization and management of genetically modified organisms, such as live animals, semen and embryos, transgenic plants, bio-control agents and seeds for agricultural production.

• The **Ministry of Health (MINSA)** is the competent national authority to regulate, control, approve and monitor the use and management of genetically modified organisms and biotechnology developments, conducted on national territory, affecting human health and the establishment of biosafety standards required for human protection.

• The **Ministry of Commerce and Industry (MICI)** is the competent national authority responsible for ensuring that negotiations and international trade agreements that involve the use of genetically modified organisms and biotechnology transfer, does not affect domestic production and investment, the environment, biodiversity and human health, and ensures the best interests of Panama.

• The **National Authority for the Environment (ANAM)** is the competent national authority for the implementation of the Cartagena Protocol on Biosafety and of the Convention on Biological Diversity, as the focal point of Panama, as well as management and environmental management of natural heritage and biodiversity of Panama. ANAM has the power to regulate and control access to and use of biogenetic resources in general, and establish, approve and monitor compliance with the rules and procedures of risk assessment for the release into the environment, monitor mitigation impacts on biodiversity and the environment, including the protected areas.

• The **Panamanian Food Safety Authority (AUPSA)** is the competent national authority that regulates and enforces the compliance of the sanitary and phytosanitary measures and quality standards related to the import, transit and transboundary movement of food and feed into Panama.

• The **National Secretariat of Science, Technology and Innovation (SENACYT),** is the competent national authority for the promotion of research for the development and transfer of biotechnology in general, and for the regulation of LMO's for use in scientific research.

• The **Authority of Aquatic Resources of Panama (ARAP)** is the entity with responsibility for the authorization, control, supervision, monitoring, and release to the aquatic environment of marine and aquatic organisms genetically modified, that are located outside the protected areas.

• The **Authority for Consumer Protection and Defense of the Competition (ADECO)** is the entity responsible for protecting and ensuring the process of free economic competition and free competition, eliminating monopolistic practices and other restrictions in the efficient functioning of markets for goods and services, monitoring the compliance of the food labeling, and to preserve the best interests of consumers in Panama.

Also, ANAM, as the focal point for the Cartagena Protocol, just received the second phase of the non-reimbursable funds from the United Nations Environmental Program (UNEP), Global Environment Funds (GEF), to help Panama in the implementation of the Cartagena Protocol on Biosafety in Panama, and its national legal framework.

b) APPROVALS:

As mentioned previously, under Resolution CNB No. 05-2012 of August 2, 2012 of the National Commission of Biosafety for Genetically Modified Organisms of Panama, published on the Official

Gazette No. 27105-A, has authorized the cultivation with DuPont-Pioneer's "Herculex I" (DAS-01507-1) Corn seeds, to the local corn producers but using the Biosafety and Management Plan for controlled planting. This plan was published at the Official Gazette No. 27340-B through the Ministry of Agricultural Development Resolution DAL -024-ADM-2013 of June 20, 2013.

c) FIELD TESTING:

The GOP conducted two official field-testing, on the agricultural crop year 2012-2013 in the province of Los Santos, Panama, using 2,011 bags of the Herculex I corn seed with the technical supervision of the Panamanian Agricultural Research Institute (IDIAP, in Spanish) and the assistance of the Panamanian importing company, Melo and Co.

On the first field-test the GOP evaluated: an assessment of pollen dispersal; assessment of populations of insects on crops of corn Herculex I; evaluation of biological efficacy; and agronomic validation. And on the second field-testing the GOP made another evaluation of biological efficacy.

d) STACKED EVENT APPROVALS: None

e) ADDITIONAL REQUIREMENTS:

Prior to use the GM Corn seed, or any other seed, it has to be registered at the National Committee of Seeds for its registration for commercialization. The National Committee of Seeds is under MIDA's structure. http://www.mida.gob.pa/direcciones/direcciones_nacionales/comite-nacional-de-semillas.html

f) COEXISTENCE:

Panama applies the following legislation which coexists for Non-GE crops (Organic Products): International standards set by the CODEX Alimentarius and ISO Guide 65 governing organic production and operation process of certifying companies producing organic products. National Legislation for Organic production: Law 8 of January 24, 2002; Executive Decree of August 11, 2004; and Ministerial Resolution No. DAL-067.ADM-05 of December 9, 2005.

g) LABELING:

At the international level, Panama supports a policy of not requiring specific mandatory labeling for biotech products, a principle also applied in Panama for all food products, as established in article 36 of Law 45 of October 31, 2007. Panama accepts the CODEX Alimentarius recommendation of voluntary labeling

h) TRADE BARRIERS:

There are no biotechnology-related trade barriers affecting U.S. exports currently.

i) INTERNATIONAL PROPERTY RIGHTS:

Panama is also a party to other International Bodies related to Intellectual Property Rights (IPR), which addresses plant patents, copyright protection, registration requirements; it is also a member of the UPOV Convention, the International Treaty on Plant Genetic Resources for Food Agriculture, among others.

The U.S-Panama Trade Promotion Agreement entered into force on October 31, 2012 also has a Chapter 15 of Intellectual Property Rights and a Chapter 17 of Environment, besides the other chapters of Market Access, Sanitary and Phytosanitary Measures and Technical Barriers to Trade, which are applicable for U.S. agricultural exports to Panama.

j) CARTAGENA PROTOCOL RATIFICATION:

Panama is an active party of the Cartagena Protocol on Biosafety, under the Convention of Biological Diversity. And Panama ratified the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress, in case of damage caused by a Living Modified Organism (LMO).

k) INTERNATIONAL TREATIES/FORA:

Panama has not negotiated to date, any type of Bilateral Agreement or Memorandum of Understanding with any other country regarding GMOs or LMOs.

Panama is a member of the International Plant Protection Convention (IPPC), the CODEX Alimentarius and the International Animal Health Organization (OIE). But, because of lack of resources to send a GOP representative to the international discussions related to GE plants and animals, it has not been very active in those discussions, except for the Cartagena Protocol discussions.

l) RELATED ISSUES: None

m) MONITORING AND TESTING:

Panama does not currently have a monitoring and testing program for GE products.

n) LOW-LEVEL PRESENCE POLICY:

Panama does not currently have a Low Level Presence (LLP) policy.

PART C: Marketing

a) MARKET ACCEPTANCE:

From time to time, local newspapers publish articles (that appear to come from foreign sources) advising of the alleged dangers to humans posed by foods prepared with GMOs, and also of the

supposedly catastrophic impact on the environment if GMOs are produced in the country. With less frequency, articles are published that talk about the benefits of GMOs and their products. For example, the Serilini study on rats using GM corn caused the Panamanian consumers association to make public statements about not trusting products made by GM corn. Fortunately, the Serilini study was refuted by the European scientific organizations, which reduced the bad public perception, due to lack of scientific and reliable information.

b) PUBLIC/PRIVATE OPINIONS:

Most agriculture professionals graduate from local universities that lack advanced training in modern developments in biotechnology. This may hurt perceptions of GMOs by many, including those who tend to distrust big industries and new methods of mass production of food products. There are two private consumers' associations that are expressing concern about lack of protection from authorities for consumers of medicines and of some imported food products, mainly from Asia. This could lead to rejection of this technology from the consumers and the public sector, depending on the information they receive in the future.

c) MARKETING STUDIES:

There have been no market studies in Panama to assess consumer acceptance of GMOs.

PART D: Capacity Building and Outreach

a) ACTIVITIES:

Education and outreach present themselves as the best alternatives to promote accurate information about GMOs in a market that clearly understands the benefits of trade and friendly relations with the United States.

The USDA's Cochran Fellowship Program has a crucial effect on the government officials selected as candidates for training in Biotechnology. FAS/Panama also has brought several speakers on Biotechnology to Panama in 2007, 2009, 2010, 2011 and 2012 to give a series of presentations to both government officials and food importers, using Department's of State EB Program for Biotechnology.

Many local technicians and government officials working in this field, including policy, teaching, and laboratory research, would greatly benefit from short term trainings in the U.S., but the language barrier has prevented this exchange. If biotechnology courses in Spanish could be provided, it would be of great benefit to improve local knowledge and create regulations based on science and risk analysis. Training on risk analysis and risk communication would benefit the GON on many levels as it would improve overall capacity to make decision on biotech events and, subsequently, communicate those decisions to the public.

For example, in the area of human health there are only certified clinical diagnostic tests, for public health diseases. There is no certified diagnostic test on transgenic organisms.

Panama has lack of physical infrastructure for research or experimental trials of GMO's in greenhouses, or confined plots, under biosafety measures.

Panama, through the UNEP – GEF Project, for representatives of the competent national authorities and academic institutions, has focused on training on the Cartagena Protocol on Biosafety and how to register and search data in the Biosafety Clearing House.

b) STRATEGIES AND NEEDS:

Panama needs specific training for Government officials on environmental risk analysis and food safety risk analysis for GMOs. Also the Government has indicated that the Panamanian Journalists need training on public outreach for GMOs and how to understand GMOs, in order to increase the acceptance of products exported from the United States.

Panama has other applied agro-biotechnologies, such as plant tissue culture, molecular biology, in vitro conservation, cryopreservation, and genetic engineering. In the health sector, there is capacity to diagnose diseases [ii] . Research at local universities focuses on tissue culture of some species of economic importance, mainly for reproduction in disease free environments. Resources have not been devoted to manipulating genes or sections of the DNA molecule as a means to produce new GMOs.

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[ii] Inter-American Institute for Cooperation on Agriculture (IICA). Agro-biotechnology in Latin America and the Caribbean. Current situation of it development and adoption. 2008. 62 pages.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART E: Production and Trade

a) BIOTECHNOLOGY PRODUCT DEVELOPMENT:

In Panama, genetic engineering in animals has been used for the development in fish tanks at Boquete, Province of Chiriqui, of AquaBounty's AquAdvantage® Salmon, which includes a gene that provides the fish with the potential to grow to market size in half the time of conventional salmon. The research of the private company, supervised by the National Commission of Biosafety for Genetically Modified Organisms of Panama has been giving positive results. However, the Government of Panama has not authorized the salmon for commercialization, nor for human consumption.

Meanwhile in the United States, the U.S. Food and Drug Administration is pending decisions on regulation and approval for human consumption. There have been several environmentalist associations which have been completely opposed to this project.

The Gorgas Memorial Institute of Tropical and Preventive Health Studies (ICGES) in Panama requested authorization for research and release to the environment of Oxitec's genetically engineered mosquitoes

Aedes aegypti to control Dengue fever in Panama. This past May, ICGES released 300,000 genetically engineered sterile male *A. aegypti* mosquitoes in Araijan district, 18 kilometers west of Panama City, as an evaluation project. Unlike females, Aedes males do not feed on blood, but flower nectar. The purpose of this project is that the transgenic male Aedes copulate with native female laying 80 to 100 eggs. Coupling with sterile males will prevent mosquitoes from reproducing and decrease their population. This biological control is safer than fumigating with insecticides the entire country.

Recently, the Panama – United States Commission for the Eradication and Prevention of Screwworm (COPEG) requested the authorization for research development and release to the environment of the genetically engineered flies *Cochliomyia hominivorax*, with a male only strain for the biological control of the Screwworm disease, which will reduce the cost of the program, for benefiting the Central American and North American livestock production.

There are no other agriculturally-relevant animals genetically engineered in Panama.

b) COMMERCIAL PRODUCTION:

The new Government Administration will have the challenge to also approve GE AquAdvantage® Salmon for commercialization, in order to be exported to the United States, once the FDA publishes its Final Rule for local consumption in the United States.

c) BIOTECHNOLOGY EXPORTS: None

d) BIOTECHNOLOGY IMPORTS:
The GE mosquitoes and salmon were imported in their first stages, and they grew until their final stages in Panama.

PART F: Policy

a) REGULATION:

No specific regulations have been developed for products of animal biotechnology. General biosafety and biotechnology laws apply for animal biotechnology in Panama.

b) LABELING AND TRACEABILITY:

Labeling regulations have not been developed for products of animal biotechnology. The new Traceability Law, which is currently under the development of its implementing regulations, may apply in the future for products of animal biotechnology.

c) TRADE BARRIERS:

There are no trade barriers at this time that would affect U.S. exports.

d) INTELLECTUAL PROPERTY RIGHTS (IPR):

Panama is a party to International Bodies related to Intellectual Property Rights (IPR), which addresses plant patents, copyright protection, registration requirements.

The U.S-Panama Trade Promotion Agreement entered into force on October 31, 2012 also has a Chapter 15 of Intellectual Property Rights.

Therefore, the above will also apply for products of animal biotechnology.

e) INTERNATIONAL TREATIES/FORA:

Panama does not have an active participation in discussions related to animal new technologies in international organizations such as OIE or OECD.

PART G: Marketing

a) MARKET ACCEPTANCE AND b) PUBLIC/PRIVATE OPINIONS:

The production of food products from genetic engineered animals is not well understood by local consumers. This reflects in the fact that lawmakers do not think this is a priority in the issuing of new regulations and therefore, there have not been any discussions of related regulatory policies for genetic engineering of animals.

MARKET STUDIES: None

PART H: Capacity Building and Outreach

a) ACTIVITIES:

No activities have been developed by Post specifically on animal biotechnology.

b) STRATEGIES AND NEEDS:
Please see plant biotechnology section on this subject.